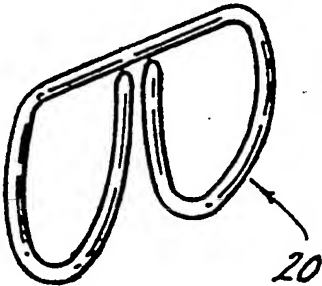


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<p>(21) International Application Number: PCT/US92/00209 (22) International Filing Date: 8 January 1992 (08.01.92) (30) Priority data: 653,353 6 February 1991 (06.02.91) US (71) Applicant: MINNESOTA MINING AND MANUFACTURING COMPANY [US/US]; 3 M Center, Post Office Box 33427, Saint Paul, MN 55133-3427 (US). (72) Inventors: VIDAL, Claude ; REDMOND, Russell, J. ; P.O. Box 33427, Saint Paul, MN 55133-3427 (US). (74) Agents: HOHENSHELL, Jeffrey, J. et al.; P.O. Box 33427, Saint Paul, MN 55133-3427 (US).</p>		<p>(81) Designated States: AT (European patent), BE (European patent), CA, CH (European patent), DE (European patent), DK (European patent), ES (European patent), FR (European patent), GB (European patent), GR (European patent), IT (European patent), JP, LU (European patent), MC (European patent), NL (European patent), SE (European patent). Published With international search report.</p>
<p>(54) Title: IMPROVED SURGICAL HARDWARE WITH BACTERIOSTATIC SILVER COATING, AND METHOD OF USING SAME</p>		
		
<p>(57) Abstract</p> <p>A staple, wire suture, clip, or other item of surgical hardware is disclosed which can be used to close a wound, made from a high strength metal to have a low profile design to minimize interference and disturbance of the wound, and having a bacteriostatic silver coating to reduce the risk of wound infection from the hardware. A method of closing surgical wounds with reduced risk of infection is also disclosed, the method includes the steps of closing the wound with a staple, wire suture, clip, or other item of surgical hardware made from a high strength metal that has a silver coating.</p>		

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IMPROVED SURGICAL HARDWARE WITH
BACTERIOSTATIC SILVER COATING, AND METHOD OF USING SAME

5 BACKGROUND OF THE INVENTION

 This invention relates to surgical hardware of the type used to close wounds, and to an improved method of closing wounds using such hardware.

10 Various items of metal hardware have been developed to assist in closing wounds. At one time such hardware was made from solid silver. However, because of silver's high ductility and relatively low strength, silver hardware had to be made very coarse to have adequate mechanical
15 properties. For many applications solid silver hardware was objectionably coarse. High strength metals such as stainless steel and titanium, permit more slender, clinically desirable hardware designs, and have for decades been the state of the art materials for surgical hardware.

20 Wound infection is always a serious concern because of its system-wide effect and retardation of normal wound healing, but when surgical hardware is required and used there are additional potential complications from wound infection including dehiscence or splitting of the wound,
25 leakage from the wound, and formation of adhesions. While conventional steel and titanium hardware can be sterilized, it does not appear to have significant bacteriostatic effect, and may actually promote infection compared with other materials. Nevertheless, because these high strength
30 metals permit the manufacture of such small, high strength hardware, these metals are still widely used.

SUMMARY OF THE INVENTION

35 The present invention provides an improved item of surgical hardware that provides the strength and compact size of a high strength metal such as stainless steel or titanium, and bacteriostatic properties to reduce the risk of wound infection. This hardware allows wounds to be

neatly and effectively closed, and provides some bacteriostatic action that reduces the risk of many of the complications encountered in the use of surgical hardware.

The invention relates to a staple, wire suture, clip, or other item of surgical hardware used in closing wounds. Generally, the surgical hardware constructed according to the principles of the present invention comprises an item of surgical hardware that is made from a high strength metal, for example stainless steel or titanium, and which has a silver coating. The silver coating may be either silver plating, or a coating of silver salt. Generally the method of closing wounds according to the present invention comprises closing the wounds with surgical hardware made from a high strength metal and which has a silver coating.

The hardware of the present invention provides all of the advantages of being constructed from a high strength metal, including high strength and compact size, and the additional benefit of bacteriostatic action which helps to reduce the risk of complications resulting from the use of the hardware. The compact design permitted by the present invention ensures that the hardware has sufficient strength to hold the wound closed, and a sufficiently compact size that it does not unduly disturb the wound site or interfere with healing. The cost of manufacturing hardware according to the principles of the present invention is only marginally higher than the cost of manufacturing conventional hardware. The method of this invention provides a way to close wounds with reduced risk of infection and complications.

These and other features and advantages will be in part apparent and in part pointed out hereinafter.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1 is a perspective view of an internal (soft tissue) staple constructed according to the principles of this invention;

FIGURE 2 is a perspective view of a skin staple constructed according to the principles of this invention;

FIGURE 3 is a perspective view of a fascia staple constructed according to the principles of this invention;

5 FIGURE 4 is a perspective view of a vascular staple constructed according to the principles of this invention;

FIGURE 5 is a perspective view of a vascular clip constructed according to the principles of this invention;

10 FIGURE 6 is a perspective view of a wire suture constructed according to the principles of this invention; and

FIGURE 7 is a cross-sectional view of the wire suture, taken along the plane of line 7-7 in Figure 6.

15 Corresponding reference numerals indicate corresponding parts throughout the several views of the drawings.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

20 Surgical staples constructed according to the principles of the present invention are indicated generally as 20, 22, 24, and 26 in Figures 1 - 4. A surgical clip constructed according to the principles of the present invention is indicated generally as 28 in Figure 5. A wire suture constructed according to the principles of the
25 present invention is indicated generally as 30 in Figure 6. Although the present invention is described with respect to staples, clips, and sutures, the invention is not so limited and relates to any item of surgical hardware of the type used to close wounds.

30 The staples 20 - 26, the clip 28, and the suture 30 are made from a high strength surgical metal such as a stainless steel or titanium. Because they are constructed of a high strength material, these items have superior strength, and more importantly they can be designed to be small and
35 compact so that they do not unnecessarily disturb the wound or interfere with proper healing. However, unlike any prior art item of surgical hardware, the staples 20 - 26, the clip 28, and the wire suture 30 have a silver coating. This is best shown in Figure 7 where the suture is shown as

comprising high strength surgical metal 32 with a silver coating 34. The silver coating provides a bacteriostatic action that inhibits infection. Thus infection is less likely to propagate when the surgical hardware of the present invention is used, and thus there is a reduced risk from infection-related complications from the use of such hardware.

The silver coating may be silver plating applied by a hot dip or electro-deposition process, or some other method. Alternatively, the coating may be a silver salt applied to the exterior of the item of hardware, for example silver nitrate, or silver-zinc allantoinate.

The method of the present invention relates to an improved method of closing surgical wounds with reduced risk of infection. The method comprises the step of closing the wound with a staple, wire suture, clip or other item of surgical hardware made from a high strength metal that has a silver coating.

The bacteriostatic effect of the hardware of this invention was tested by introducing a silver coated staple according to the principles of this invention, a stainless steel staple, and titanium staple into two difference agar media: Trypticase Soy Sheep Agar and Mueller Hinton Agar. Each of the staples was screened against staph aureus, Escherichia coli, Pseudomonas aeriginosa, and strep faecales. The plates were inoculated with a standard turbidity of a 0.5 McFarland standard. The staples were placed on top of the agar and the plates were incubated at 35°C for 24 hours. As illustrated in the following table, only the silver coated staple of the present invention showed any bacteriostatic action showing a zone of inhibition around the staple.

		Staph aureus		Escherichia Coli		Pseudomonas Aeriginosa		Strep Faecales	
35	Silver Plated	TSS Agar 11mm	M-H Agar 11mm	TSS Agar 6mm	M-H Agar ...	TSS Agar 22mm?	M-H Agar ...	TSS Agar ...	M-H Agar ...
40	Stainless Steel
	Titanium

In view of the above, it will be seen that the several objects of the invention are achieved and other advantageous results attained.

5 As various changes could be made in the above constructions without departing from the scope of the invention, it is intended that all matter contained in the above description or shown in the accompanying drawings shall be interpreted as illustrative and not in a limited
10 sense.

WHAT IS CLAIMED IS:

1. An improved staple, wire suture, clip, or other metallic item of surgical hardware of the type made from a high strength metal such as stainless steel or titanium, the improvement comprising a silver coating on the surface of the hardware.
2. The hardware according to claim 1 wherein the silver coating comprises silver plating.
3. The hardware according to claim 1 wherein the silver coating comprises silver salts.
4. A staple, wire suture, clip, or other item of surgical hardware used to close a wound, made from a high strength metal to have a low profile design to minimize interference and disturbance of the wound, and having a bacteriostatic silver coating to reduce the risk of wound infection from the hardware.
5. The hardware according to claim 4 wherein the silver coating comprises silver plating.
6. The hardware according to claim 4 wherein the silver coating comprises silver salts.
7. A method of closing surgical wounds with reduced risk of infection comprising the step of closing the wound with a staple, wire suture, clip or other item of surgical hardware made from a high strength metal that has a silver coating.
8. The method according to claim 4 wherein the silver coating comprises silver plating.
9. The method according to claim 4 wherein the silver coating comprises silver salts.

10. A surgical staple having bacteriostatic coating.

11. A surgical staple according to claim 1 wherein said bacteriostatic coating is silver.

FIG. 1.

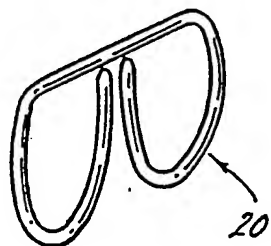


FIG. 2.

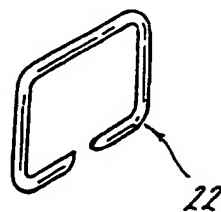


FIG. 3.

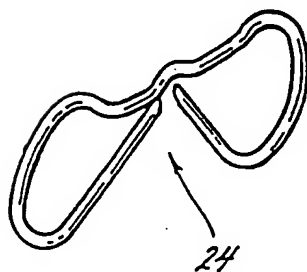


FIG. 4.

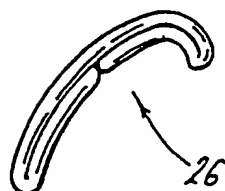


FIG. 7.

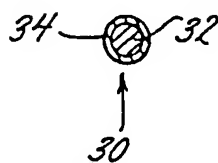


FIG. 5.

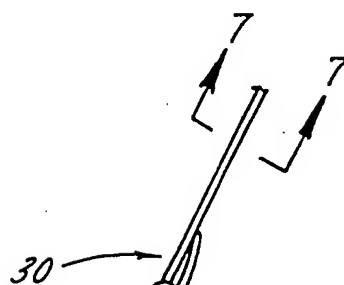
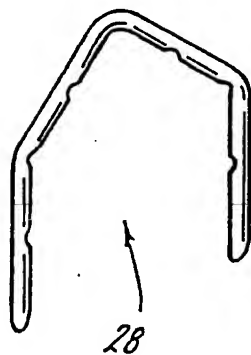
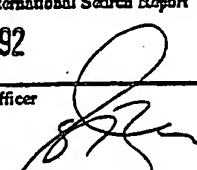


FIG. 6.

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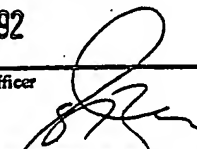
International Application No

I. CLASSIFICATION OF SUBJECT MATTER (If several classification symbols apply, indicate all) ⁶		
According to International Patent Classification (IPC) or to both National Classification and IPC		
Int.Cl. 5 A61B17/064		
II. FIELDS SEARCHED		
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Int.Cl. 5	A61B	
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched ⁸		
III. DOCUMENTS CONSIDERED TO BE RELEVANT⁹		
Category ¹⁰	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³
X	EP,A,0 206 024 (BECTON) 30 December 1986 see claims 1,4,11,12,14 ---	1-11
A	EP,A,0 255 248 (MINNESOTA) 3 February 1988 see abstract ---	3,6,9
A	CH,A,654 738 (BLÄTTLER) 14 March 1986 ---	
A	WO,A,8 102 668 (BURFORD) 1 October 1981 ---	
A	EP,A,0 328 421 (COLUMBIA) 16 August 1989 ---	
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International Searching Authority	Signature of Authorized Officer	
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INTERNATIONAL SEARCH REPORT

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International Application No.

I. CLASSIFICATION OF SUBJECT MATTER (If several classification symbols apply, indicate all) ⁶		
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A	WO,A,8 102 668 (BURFORD) 1 October 1981 ---	
A	EP,A,0 328 421 (COLUMBIA) 16 August 1989 ---	
A	EP,A,0 046 715 (USSC) 3 March 1982 ---	
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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP-A-0206024	30-12-86	US-A- 4886505	12-12-89
		AU-A- 3155089	29-06-89
		AU-B- 588598	21-09-89
		AU-A- 5841786	11-12-86
		JP-B- 2005089	31-01-90
		JP-A- 62002947	08-01-87
EP-A-0255248	03-02-88	US-A- 4728323	01-03-88
		AU-B- 595333	29-03-90
		AU-A- 7427987	28-01-88
		CA-A- 1279573	29-01-91
		JP-A- 63035260	15-02-88
CH-A-654738	14-03-86	None	
WO-A-8102668	01-10-81	EP-A, B 0048246	31-03-82
		EP-A, B 0048247	31-03-82
		WO-A- 8102667	01-10-81
		GB-A, B 2072514	07-10-81
		GB-A, B 2073024	14-10-81
		US-A- 4476590	16-10-84
		US-A- 4615705	07-10-86
EP-A-0328421	16-08-89	US-A- 5019096	28-05-91
		AU-A- 2989589	17-08-89
		JP-A- 2017071	22-01-90
		AU-A- 7922991	03-10-91
EP-A-0046715	03-03-82	AT-T- 7848	15-06-84
		AU-A- 7101681	04-03-82
		CA-A- 1170536	10-07-84
		DE-C- 3152256	21-02-85
		GB-A, B 2100821	06-01-83
		WO-A- 8200582	04-03-82
		US-A- 4407286	04-10-83
EP-A-0406014	02-01-91	AU-A- 5788390	03-01-91
		CA-A- 2020075	31-12-90
		JP-A- 3066378	22-03-91